K092479

Premarket Notification [510(k)] Summary

JAN 11 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K092479

Company: DYN'R SAS
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31600 MURET
France

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Contact Person: Xavier ISNARD

Date Prepared: 12th august 2009

Device Names:

Trade/Proprietary Name:	**SDX – SpiroDynr'X Radiotherapy Breathing Control**
Common or Usual Name:	**Patient Breathing Control system**
Device Class:	**Class II**
Classification Name:	**21 CFR §892.5050**
Product Code:	**IYE Accessory to Medical Charged Particle Radiation Therapy system**

Substantial Equivalence:
The data and information supplied in this submission demonstrates substantial equivalence to the Active Breathing Coordinator ABC System by Aktina Medical Physics (K003330)

Description:
SDX is a spirometer located in the imaging or treatment room, with software installed on a dedicated workstation located in the control room.
In the voluntary breath hold technique, the patient is independently monitoring their breathing pattern and reproduces the effective breath hold level. The patient holds their breath at a defined volumetric level whilst imaging or radiation therapy is being carried out under the Clinical team supervision.

Intended Use :
SDX – SpiroDynr'X is intended for use in Radiation therapy as an aid in allowing the patient and treatment staff to visualize a patients breathing process and to optimize the time when a breath should be held to limit internal motion during treatment.

Discussion of Performance Data:
Performances tests on linearity and stability of the pulmonary volume measures demonstrated that the SDX SpiroDynr'X was found to be well within the required specifications.
SDX SpiroDynr'X is compliant with IEC 60601-1 Electrical Safety of Medical Electrical Device and IEC 60601-1-2 ElectroMagnetic Compatibility of Medical Electrical Device.

Conclusion for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices is not compromised and that it meets all acceptance criteria, demonstrating that the device can be considered substantially equivalent to the predicate device.

05 003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 22 2010

Mr. Xavier Isnard
Regulatory Affairs Manager
Dyn'R
73, rue de Louge
MURET Haute-Garonne 31600
FRANCE

Re: K092479
Trade/Device Name: SDX – SpiroDynr'X
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 8, 2009
Received: December 11, 2009

Dear Mr. Isnard:

This letter corrects our substantially equivalent letter of January 11, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

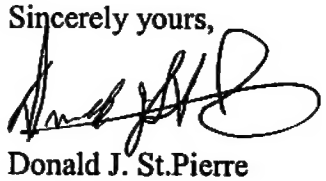
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092479

Device Name: SDX – SpiroDynr'X

Indications for Use:

SDX – SpiroDynr'X is intended for use in Radiation therapy as an aid in allowing the patient and treatment staff to visualize a patients breathing process and to optimize the time when a breath should be held to limit internal motion during treatment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092479